

EXHIBIT “D”



(12)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUL - 9 1991

Mr. Anthony Filandro
Virginia Dare Extract Co. Inc.
882 Third Avenue
Brooklyn, New York 11232

Dear Mr. Filandro:

This responds to your letter dated June 14, concerning the use of the term "natural" when applied to vanillin obtained: (1) from the curcumin in turmeric oleoresin, and (2) by means other than direct extraction of vanillin in botanical materials, e.g. by conversion of eugenol in clove oil.

As you know vanillin is considered a GRAS synthetic flavoring substance/adjuvant and it is regulated under 21 CFR 182.60. The specifications for vanillin are listed in the Food Chemicals Codex. The process described in your correspondence describes manufacturing vanillin from turmeric oleoresin suspension in water which is heated with diethylene glycol dimethyl ether at 316°C and 1680 psi. These processing conditions per se meet the criteria set for the in 21 CFR 101.22(a)(3) for obtaining "natural" flavors. However, this vanillin would not qualify as "natural vanillin," as defined in 21 CFR 101.22(a)(3), because the vanillin is not obtained from vanilla beans, whose flavor it simulates.

It is our understanding from available standard references, that the traditional process by which vanillin is obtained from the eugenol in clove oil involves the use of various chemical reactants, and that this is not one of the physical processes described in 21 CFR 101.22(a)(3). Consequently, vanillin obtained from the eugenol in clove oil would not be considered "natural vanillin."

Copies of the above regulations are attached for your information. If we can be of any further assistance, please let us know.

Sincerely yours,

Manjeet Singh
Assistant to the Director
Division of Regulatory Guidance
Center for Food Safety and
Applied Nutrition

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